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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,746

Applicant(s)

WINCHESTER ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004 and 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10,13-15,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,8-10,13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/8/2003 and 2/10/2004 has been entered.

2. Claims 18 and 19 are under consideration.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite in the recitation of "indicated for treating rheumatoid arthritis" because it is unclear what this means or encompasses in the context recited in the claim. It is unclear if "indicated for treating rheumatoid arthritis" refers to an intended use or that it implies that there is some sort of label and/or instruction that communicates this intended use and that this label and/or instruction is supplied with the composition. Regarding applicants comments, the Examiner takes the position that while this term is indefinite, it could be interpreted as an intended use for the composition wherein the composition does not contain a label or instructions per se. Furthermore, virtually no prescription drug has a label which indicates an intended use. Furthermore, use of common drugs for "off use" purposes is also found wherein the label or instructions do not communicate a common use. For example, low dose enteric coated aspirin is commonly used for its putative cardiac disease preventive properties, yet this use is not elucidated on the label or accompanying instructions.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of of "indicated for treating rheumatoid arthritis" in claim 18. Regarding applicants comments about "composition for treating rheumatoid arthritis", this phrase implies that the composition is used for treating rheumatoid arthritis. It does not indicate that the composition has a label or instructions for treating rheumatoid arthritis. Said limitation indicates nothing more than an intended use. It is unclear if "indicated for treating rheumatoid arthritis" refers to an intended use or that it implies that there is some sort of label and/or instruction that communicates this intended use and that this label and/or instruction is supplied with the composition. To the extent that term indicates anything other than an intended use it constitutes new matter because there is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. Schols et al. teach a bicyclam (AMD3100) and said compound in a carrier/pharmaceutically acceptable carrier (eg. media used to dissolve said compound

or PBS)(see page 147 and page 149, second column, first complete paragraph and Figure 2).

Regarding applicants arguments, "indicated for treating rheumatoid arthritis" while indefinite for the reasons stated above is being interpreted as an intended use for the purposes of this product claim. The recitation of an intended use carries no patentable weight in the instant product claims.

9. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by De Vreese et al. as evidenced by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. De Vreese et al. teach the bicyclam JM3100 and said compound in a carrier/pharmaceutically acceptable carrier (eg. media used to dissolve said compound)(see page 210 and section 2.3). Schols et al. disclose that JM3100 is another name for AMD3100 (see page 147, second column).

Regarding applicants arguments, "indicated for treating rheumatoid arthritis" while indefinite for the reasons stated above is being interpreted as an intended use for the purposes of this product claim. The recitation of an intended use carries no patentable weight in the instant product claims.

10. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Murrer et al. (US Patent 5,021,409)

The recitation of an intended use carries no patentable weight in the instant product claims. The recitation of a method of making the claimed compound/composition carries no patentable weight in the instant product claims. Murrer et al. teach bicyclams in a carrier/pharmaceutically acceptable carrier (see column 1, third paragraph, column 2, penultimate paragraph and claims 7 and 8).

Regarding applicants arguments, "indicated for treating rheumatoid arthritis" while indefinite for the reasons stated above is being interpreted as an intended use for the purposes of this product claim. The recitation of an intended use carries no patentable weight in the instant product claims.

11. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Datema et al. as evidenced by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. Datema et al. teach the bicyclam JM3100 and said compound in a carrier/pharmaceutically acceptable carrier at a variety of different concentrations (see page 751, column 2). Schols et al. disclose that JM3100 is another name for AMD3100 (see page 147, second column).

Regarding applicants arguments, "indicated for treating rheumatoid arthritis" while indefinite for the reasons stated above is being interpreted as an intended use for the purposes of this product claim. The recitation of an intended use carries no patentable weight in the instant product claims.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644



RONALD B. SCHWADRON

PRIMARY EXAMINER

GROUP 1800-1600